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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/896,186	06/29/2001	Joshua Levin	PB/5-31481A	9567

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EXAMINER

MEHTA, ASHWIN D

ART UNIT	PAPER NUMBER
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1638

DATE MAILED: 09/22/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/896,186

Applicant(s)

LEVIN ET AL.

Examiner

Ashwin Mehta

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– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 25-28, 38, 39, 44, 47, 51, 52 and 58-60 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 25-28, 38, 39, 44, 47, 51, 52 and 58-60 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 05 November 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6272005</u> | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The objection to claim 60 is withdrawn in light of the claim amendment.
3. The rejection of claim 52 under 35 U.S.C. 112, 2nd paragraph is withdrawn in light of the claim amendment.

Claim Rejections - 35 USC § 112

4. Claims 25-28, 38, 39, 44, 47, 51, 52, and 58-60 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention, for the reasons of record stated in the Office action mailed January 28, 2005. Applicants traverse the rejection in the paper filed June 23, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Applicants argue that the specification does describe a written description of the invention in that SEQ ID NO: 23 is the DNA sequence encoding SEQ ID NO: 24, and that the specification describes the gene when it provides the sequence of SEQ ID NO: 23 (response, paragraph bridging pages 5-6). However, the transgenic plant cell of the claims comprise an endogenous nucleotide sequence encoding SEQ ID NO: 24, comprising a mutation, or in a

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regulatory region thereof. SEQ ID NO: 23 is a cDNA sequence, not an endogenous nucleotide sequence. The last two lines of page 17 of the specification indicate that an endogenous nucleotide sequence is a sequence present in the genome of an untransformed plant cell. Further, the endogenous nucleotide sequence, or regulatory region thereof, of the claimed plant cell must comprise a mutation. SEQ ID NO: 23 is not a mutated sequence.

Applicants also argue that while Example 5 is written in the present tense, the experiments discussed therein were carried out and results presented in Table 3. Applicants argue that a transgenic plant with a mutation in SEQ ID NO: 23 is described in Example 5 (response, page 6, 2nd full paragraph). However, Example 5 discusses the analysis of expression of GFP in the progeny of a cross between transgenic Arabidopsis line “8Z-2”, which comprises a post-transcriptionally silenced GFP transgene, and line “S11.13-34”, which comprises T-DNA insertion 26 bp 5’ of the predicted coding region of SEQ ID NO: 1 (Example 2). The transgenic plants of Example 5 do not comprise SEQ ID NO: 23, and Example 5 does not describe any mutation of SEQ ID NO: 23. Applicants argue the Example 7 describes that the insertional mutation was found in SEQ ID NO: 1, the sequence of which is also in GenBank Accession No. At4g13870. Applicants also argue that the corresponding cDNA is SEQ ID NO: 23, which sequence differs from SEQ ID NO: 1, and that the protein sequence in SEQ ID NO: 24 comprises a predicted translation of bases 42-905 of SEQ ID NO: 23 (response, page 6, 4th full paragraph). However, the claims require the mutation in the transgenic plant cell to be in an endogenous nucleotide sequence encoding SEQ ID NO: 24, or a regulatory region thereof. SEQ ID NO: 1 does not encode SEQ ID NO: 24. Applicants themselves have admitted that the cDNA, SEQ ID NO: 23, differs from the GenBank annotation, SEQ ID NO: 1. Further, the

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amino acid sequence of SEQ ID NO: 2, encoded by SEQ ID NO: 1 (specification, page 46, lines 6-7), differs from SEQ ID NO: 24. The specification does not describe an endogenous nucleotide sequence encoding SEQ ID NO: 24, nor any regulatory sequence thereof, and therefore a plant cell comprising a mutation in said endogenous nucleotide sequence or regulatory region thereof. Further, claim 25 does not place any limit on the effect of the mutation on expression of the endogenous nucleotide sequence, and therefore encompasses increasing its expression, which would not relieve post-transcriptional gene silencing of any silenced transgene.

Further, claims 52 and 60 require the endogenous nucleotide sequence to comprise SEQ ID NO: 23. However, SEQ ID NO: 23 is a cDNA sequence, differs from SEQ ID NO: 1, and is not an endogenous nucleotide sequence.

5. Claims 25-28, 38, 39, 44, 47, 51, 52, and 58-60 remain rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention, for the reasons of record stated in the Office action mailed January 28, 2005. Applicants traverse the rejection in the paper filed June 23, 2005. Applicants' arguments have been fully considered but were not found persuasive.

Applicants again state the experiment discussed in Example 5 was actually performed, admit that Example 9 is prophetic, but that results of the experiment of Example 9 is set forth in post-filing art, Glazov et al. (response, page 7, 2nd and 3rd full paragraphs). Applicants point out that SEQ ID NO: 1 is the genomic version of the gene encoding SEQ ID NO: 24 (response, page

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7, 4th full paragraph). However, SEQ ID NO: 1 does not encode the entire amino acid sequence of SEQ ID NO: 24. The alignment provided by Applicants themselves shows that there are differences between SEQ ID NOs: 2 and 24. Applicants point out that SEQ ID NO: 1 is the genomic version of the gene encoding SEQ ID NO: 2 (response, page 7, 4th full paragraph). However, SEQ ID NO: 1 does not encode the entire amino acid sequence of SEQ ID NO: 24. Applicants state that SEQ ID NOs: 2 and 24 are virtually identical, and align from amino acids 1-277 (response, page 7, 5th full paragraph). However, they are not entirely the same sequence, and the claims specifically require the endogenous nucleotide sequence to encode SEQ ID NO: 24. An amino acid sequence that falls even one residue short is not SEQ ID NO: 24.

Applicants argue, in response to the issue that the T-DNA insertion in the endogenous nucleotide sequence must be in both copies to lead to an increase in expression of an exogenous nucleotide sequence of interest, that the claims have been amended to recite that the plant showing increased gene expression is homozygous for the mutated gene (response, page 8, 2nd full paragraph). However, no such amendment has been made.

Summary

6. The claims are deemed free of the prior art, given the failure of the prior art to teach or fairly suggest an endogenous nucleotide sequence encoding the amino acid sequence of SEQ ID NO: 24.

7. Claims 25-28, 38, 39, 44, 47, 51, 52, and 58-60 remain rejected.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Contact Information

Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M. to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Gary Jones, can be reached at 571-272-0745. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>.

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September 13, 2005

A handwritten signature in black ink, appearing to read 'A. D. Mehta', with a stylized, cursive script.

Ashwin D. Mehta, Ph.D.
Primary Examiner
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